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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,695	<b>Applicant(s)</b> KUMAZAWA ET AL.
	<b>Examiner</b> SCARLETT GOON	<b>Art Unit</b> 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 October 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 30,32 and 34 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 30,32 and 34 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/06/08)  
Paper No(s)/Mail Date \_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_

**DETAILED ACTION**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action, dated 17 August 2009, is withdrawn.

This Office Action is in response to Applicants' Amendment and Remarks filed on 23 October 2009 in which claims 1-29, 31, 33 and 35-59 were cancelled.

Claims 30, 32 and 34 are pending in the instant application and are examined on its merits herein.

***Priority***

This application is a National Stage entry of PCT/JP05/03234 filed on 21 February 2005 and claims priority to Japan foreign application 2004-043481 filed on 19 February 2004. A certified copy of the foreign priority document in Japanese has been received. An English translation of the foreign priority document and a statement certifying the accuracy of the translation was received on 23 October 2009. Thus, Applicants' have perfected their claim to foreign priority.

***Objections Withdrawn***

Applicants' amendment and arguments, filed 23 October 2009, with respect to the objection of claims 30, 32 and 34 for depending upon a withdrawn claim, has been fully considered and is persuasive because Applicants' amendment filed on 24 April

2009 had properly amended the claims to be of independent form, as shown in the instant claims.

In view of the cancellation of claims 1-29, 31, 33 and 35-59, all objections made with respect to claims 1-29, 31, 33 and 35-59 in the previous Office Action are withdrawn.

These objections have been **withdrawn**.

***Rejections Withdrawn***

Applicants' arguments, filed 23 October 2009, with respect to the rejection of claims 30, 32, 34, 50 and 55-59 under 35 USC § 103(a), as being unpatentable over PG Pub No. US 2006/0211856 A1 to Tsuji *et al.*, in view of U.S. Patent No. 5,672,693 to Kawahara, in view of journal publication by Kawano *et al.*, have been fully considered and are persuasive because Applicants have perfected their claim to foreign priority. Thus, the earliest priority date of the instant application is now 19 February 2004. The earliest possible effective filing date of PG Pub No. US 2006/0211856 A1 to Tsuji *et al.* is 28 December 2004. Thus, PG Pub No. US 2006/0211856 A1 to Tsuji *et al.* is no longer applicable as a prior art document in view of Applicants' perfecting their foreign priority claim. This rejection has been **withdrawn**.

Applicants' arguments, filed 23 October 2009, with respect to the rejection of claims 30, 32, 34, 50 and 55-59 under 35 USC § 103(a), as being unpatentable over journal publication by van Dommelen *et al.*, in view of journal publication by Wu *et al.*, in view of U.S. Patent No. 5,672,693 to Kawahara, in view of journal publication by

Kawano *et al.*, have been fully considered and are persuasive because Applicants have perfected their claim to foreign priority. Thus, the earliest priority date of the instant application is now 19 February 2004. The publication date of Wu *et al.* is 1 February 2005. Thus, Wu *et al.* is no longer applicable as a prior art document in view of Applicants' perfecting their foreign priority claim. This rejection has been **withdrawn**.

Applicants' arguments, filed 23 October 2009, with respect to the rejection of claims 30, 32, 34, 40, 42 and 52 under 35 USC § 103(a), as being unpatentable over journal publication by Kakimi *et al.*, in view of journal publication by Wu *et al.*, and journal publication by Wiese *et al.*, as evidenced by Trinchieri *et al.*, have been fully considered and are persuasive because Applicants have perfected their claim to foreign priority. Thus, the earliest priority date of the instant application is now 19 February 2004. The publication date of Wu *et al.* is 1 February 2005. Thus, Wu *et al.* is no longer applicable as a prior art document in view of Applicants' perfecting their foreign priority claim. This rejection has been **withdrawn**.

Applicants' arguments, filed 23 October 2009, with respect to the rejection of claims 30, 32, 34, 36, 38, 40 and 52 under 35 USC § 103(a), as being unpatentable over journal publication by Kitamura *et al.*, in view of journal publication by Wu *et al.*, and journal publication by Wiese *et al.*, have been fully considered and are persuasive because Applicants have perfected their claim to foreign priority. Thus, the earliest priority date of the instant application is now 19 February 2004. The publication date of Wu *et al.* is 1 February 2005. Thus, Wu *et al.* is no longer applicable as a prior art

document in view of Applicants' perfecting their foreign priority claim. This rejection has been **withdrawn**.

In view of the cancellation of claims 1-29, 31, 33 and 35-59, all rejections made with respect to claims 1-29, 31, 33 and 35-59 in the previous Office Action are withdrawn. These rejections have been **withdrawn**.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

#### **Section [0001]**

Claims 30, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by PG Pub No. US 2002/0037291 A1 to Kawahara *et al.* (hereinafter referred to as the '704 patent; PTO-892, Ref. A).

Kawahara *et al.* disclose glycosphingolipids that exhibit moisturizing and immuno-enhancing activity. The glycosphingolipids are extracted from the *Sphingomonas* sp. and have the structures as set forth in formula (I) (paragraphs 013-0018). The glycosphingolipids typically exhibit moisturizing effect and immuno-enhancing activity, which allow them to be used for cosmetic and pharmaceutical compositions (paragraph 0035). The cosmetic or pharmaceutical composition

containing the glycosphingolipid can be in any form, such as a solid, liquid, paste, jelly or powder (paragraph 0036). The cosmetic or pharmaceutical composition can be used in toilet soaps, face washes, rinses, eye creams, sunscreen lotions, suntan creams, hair washes, lip creams, etc. (paragraph 0037). Although not explicitly indicated, since Kawahara *et al.* disclose that the compounds are useful as a cosmetic or pharmaceutical composition, and further discloses the use of the glycosphingolipid in different compositions, it is the Office's position that this compound is intended for administration to a mammal. The courts have stated that "when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

It is furthermore noted that the Kawahara '704 patent does not explicitly disclose that the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production. However, whether the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production or not, is considered a mere mechanism of action of the glycosphingolipid. The recitations "activating NKT cells," "accelerating IL-4 production," and "accelerating IFN- $\gamma$  production," in the claim is considered to be merely a mechanism of the action of the application. Applicants' recitation of a new mechanism of action for the prior art method would not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Note that a mechanism of action of a treatment

would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

Thus, the disclosure of glycosphingolipids extracted from the *Sphingomonas* sp. and their use as a cosmetic or pharmaceutical composition necessarily meets the instant claim limitations.

### **Section [0002]**

Claims 30, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,348,201 B1 to Murata *et al.* (hereinafter referred to as the '201 patent; PTO-892, Ref. B).

The Murata '201 patent discloses external compositions for the skin comprising glycosphingolipids extracted from the *Sphingomonas* sp. (column 2, lines 26-37). The compositions have potent moisturizing and skin roughness preventive effects (column 2, lines 12-15). The glycosphingolipids have the structures as set forth in formula (I) (column 2, line 38 – column 3, line 67). The external composition for the skin is available as toilet soaps, eye creams, sun-screening lotions, suntan creams, ointment, medicated lip cream, etc. (column 4, lines 1-13). The Murata '201 patent further discloses application of the external composition to the skin, hair or fingernails (claim 23). Although not explicitly indicated, since the Murata '201 patent discloses that the compositions are applied to the skin, hair or fingernails, it is the Office's position that this compound is intended for administration to a mammal. The courts have stated that "when considering a prior art method, the anticipation doctrine examines the natural and

inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

It is furthermore noted that the Murata '201 patent does not explicitly disclose that the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production. However, whether the glycosphingolipid activates NKT cells, IL-4 production, or IFN- $\gamma$  production or not, is considered a mere mechanism of action of the glycosphingolipid. The recitations "activating NKT cells," "accelerating IL-4 production," and "accelerating IFN- $\gamma$  production," in the claim is considered to be merely a mechanism of the action of the application. Applicants' recitation of a new mechanism of action for the prior art method would not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Note that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

Thus, the disclosure of glycosphingolipids extracted from the *Sphingomonas* sp. and their use as an external composition for the skin necessarily meets the instant claim limitations.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,672,693 to Kawahara (hereinafter referred to as the '693 patent; PTO-892, Ref. C), as evidenced by journal publication by Laloux *et al.* (PTO-892, Ref. U), in view of journal publication by Nicoara *et al.* (PTO-892, Ref. V).

The Kawahara '693 patent discloses glycosphingolipids isolated from the *Sphingomonas* sp. The compounds are denoted as GSL-1, GSL-2, GSL-3, and GSL-4 and their structures are shown in columns 3-6. The Kawahara '693 patent teaches that the glycosphingolipid compounds exhibit a B cell activating effect and a differentiation-deriving effect on animal cells, as determined from their cell mitogenic activity in spleen cells prepared from the spleen of 7 week old mice (column 11, lines 16-32). Thus, the Kawahara '693 patent states that the glycosphingolipids are expected to be useful as an immunoactivator (column 7, lines 55-59).

It is noted that the Kawahara '693 patent does not explicitly disclose that the immunoactivator activates NKT cells, IL-4 production, or IFN- $\gamma$  production. However, how the glycosphingolipid immunoactivators act is considered a mere mechanism of action of the glycosphingolipid immunoactivators. Applicants' recitation of a new mechanism of action for the prior art method would not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. In the instant case, the prior art reference teaches that the compound is an immunoactivator, but does not explicitly teach what part of the immune system it is activating. However, as evidenced by Laloux *et al.*, NKT cells are present in mice spleen, which also produces IFN- $\gamma$  and IL-4 upon activation. Furthermore, Applicants are requested to note that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

The teachings of the Kawahara '693 patent differ from the instantly claimed invention in that the Kawahara '693 patent does not teach administration of the glycosphingolipids to a mammal.

Nicoara *et al.* teach that immunomodulators have been used to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases (p. 303, column 2, last paragraph). Furthermore, the field of clinical immunomodulation further holds promise in the treatment of immunodeficiency diseases, infections, and cancers (p. 304, column 1, first incomplete paragraph).

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the Kawahara '693 patent, concerning the use of glycosphingolipids from the *Sphingomonas* sp. as immunoactivators, with the teachings of Nicoara *et al.*, regarding the use of immunomodulators to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases. Since the Kawahara '693 patent teaches that the disclosed glycosphingolipids can be used as immunoactivators, and Nicoara *et al.* teach that immunomodulators are used to stimulate the defense mechanisms for treatment of viral, bacterial, parasitic and fungal diseases, one of ordinary skill in the art would have been motivated to use the glycosphingolipids disclosed in the Kawahara '693 patent as immunoactivators in the treatment of viral, bacterial, parasitic and fungal diseases with a reasonable expectation of success since the glycosphingolipids are taught to have the desired function for use in the treatment of the said diseases. Furthermore, since the Kawahara '693 patent shows that the glycosphingolipids have cell mitogenic activity in spleen cells, Applicants

are requested to note that the courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. See MPEP § 2107.01. Moreover, the Federal Circuit, in *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985), commented on the significance of data from *in vitro* testing that showed pharmacological activity by stating that “[w]e perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.”

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30, 32 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,348,201 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to an external composition for the skin comprising a sphingoglycolipid extracted from the bacterium *Sphingomonas*. Structures of the sphingoglycolipids are identified in claim 16. The external composition takes various forms, including as a medicated lip cream or anti-atopic agent. The patent further claims application of the external composition to the skin, hair, or fingernails.

The claims of the instant application are drawn to a method of activating NKT cells, IL-4 production, or IFN- $\gamma$  production, which comprises administering to a mammal a cell activator comprising a glycosphingolipid having the structure as shown in the instant claims.

Thus, the instant claims 30, 32 and 34 are seen to be anticipated by claims 1-23 of U.S. Patent No. 6,348,201 B1.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-

270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

SCARLETT GOON  
Examiner  
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